



## General

### Guideline Title

Rivaroxaban for treating pulmonary embolism and preventing recurrent venous thromboembolism.

### Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Rivaroxaban for treating pulmonary embolism and preventing recurrent venous thromboembolism. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. 46 p. (Technology appraisal guidance; no. 287).

### Guideline Status

This is the current release of the guideline.

## Recommendations

### Major Recommendations

Rivaroxaban is recommended as an option for treating pulmonary embolism (PE) and preventing recurrent deep vein thrombosis and PE in adults.

### Clinical Algorithm(s)

This guidance has been incorporated into a NICE Pathway for venous thromboembolism, available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) .

## Scope

### Disease/Condition(s)

- Pulmonary embolism (PE)
- Recurrent venous thromboembolism (VTE)

### Guideline Category

Assessment of Therapeutic Effectiveness

Prevention

Treatment

## Clinical Specialty

Emergency Medicine

Family Practice

Hematology

Internal Medicine

Preventive Medicine

Pulmonary Medicine

## Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To assess the clinical effectiveness and cost-effectiveness of rivaroxaban for treating pulmonary embolism (PE) and preventing recurrent venous thromboembolism (VTE)

## Target Population

Adult patients with pulmonary embolism (PE) at risk for recurrent venous thromboembolism (VTE)

Note: The decision problem does not include patients with severe renal disease or with an increased risk of bleeding, or patients who are haemodynamically unstable.

## Interventions and Practices Considered

Rivaroxaban

## Major Outcomes Considered

- Clinical effectiveness
  - Symptomatic recurrent venous thromboembolism (VTE)
  - Clinically relevant major and non-major bleeding and other adverse events
  - Treatment satisfaction
  - Net clinical benefit
  - Time in target range with low molecular weight heparin+vitamin K antagonist (LMWH+VKA)
  - Healthcare resource utilisation outcomes (duration of hospital stay, visits to healthcare providers, diagnostic procedures)
- Cost-effectiveness

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

## Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The Evidence Review Group (ERG) report for this technology appraisal was prepared by Southampton Health Technology Assessments Centre (SHTAC) (see the "Availability of Companion Documents" field).

### Clinical Effectiveness

#### Description of Manufacturer's Search Strategy

The manufacturer conducted separate literature searches for: clinical effectiveness studies, studies to be considered for an indirect comparison/mixed treatment comparison, cost-effectiveness studies, health-related quality of life (HRQoL), and costs and resources. The ERG considers these literature searches fit for purpose. Search methodology was documented transparently by the manufacturer, with satisfactory database selection (see below, though for the sake of completeness perhaps Institute for Scientific Information [ISI] Web of Science could have been used in all searches). All strategies comprise appropriate utilisation of free text, index terms, randomised controlled trial (RCT), cost and quality of life related search filters, and were appropriately combined into sets.

For the clinical-effectiveness search the manufacturer included all of the databases required by NICE, plus CINAHL and Bayer's in-house clinical trials database (Trialfinder). The search strategy in the manufacturer's submission (MS) is transparent and reproducible. Reference lists of included articles, key review papers and relevant guidelines were also checked for other relevant studies. Additional searching for conference material on databases such as Web of Science or Zetoc was not undertaken in the clinical searches (though not mentioned as a pre-requisite for this section by NICE).

The indirect and mixed treatment comparisons search was based on a Cochrane systematic review of anticoagulation in patients with cancer, and included the NICE required databases plus ISI Web of Science. The American Society for Clinical Oncology and the American Society of Hematology were hand searched with supplementary PubMed searches.

The manufacturer's cost-effectiveness search was an update of the search conducted by the National Clinical Guideline Centre (NCGC), which informed the NICE guideline. This search covered all of NICE's required databases, plus also the NICE website was searched to identify any relevant economic models.

The clinical effectiveness searches across Medline, Embase and Medline In-Process was re-run by the ERG Information Scientist, as a benchmark, and produced a similar return of results allowing for different database start dates. The other searches documented were not re-run as they also appeared to be of good quality.

The manufacturer did not report searching on-going clinical trials databases for studies recently completed or in progress. The ERG Information Scientist searched the following clinical trials registries: UK clinical research network (UKRCN) Study Portfolio and ClinicalTrials.gov. The US Food and Drug Administration (FDA) and European Medicines Agency (EMA) websites were also checked. The results were examined by an ERG researcher with nothing additionally relevant being identified, confirming the manufacturer's statement that no completed or ongoing studies of rivaroxaban for pulmonary embolism and venous thromboembolism are likely to be available in the next 12 months.

The manufacturer also reports systematic searches for particular economic model input parameters (e.g., complications of venous thromboembolism [VTE]). Brief details of these searches are given (e.g., databases) but full search strategies are not supplied. A reference is given for these searches to an unpublished systematic review conducted by IMS Health for Bayer. The ERG has not appraised these searches.

## Statement of the Inclusion/Exclusion Criteria Used in the Study Selection

The inclusion and exclusion criteria for the clinical effectiveness systematic review are clearly stated in the MS. The criteria generally reflect the decision problem and, in turn, the NICE scope. The population is defined as 'patients with symptomatic pulmonary embolism (PE)' whereas the NICE scope specifies 'people with pulmonary embolism', so the inclusion criteria therefore does not appear to include patients who have had a PE who may no longer be symptomatic following treatment, but could be at risk of recurrent VTE (prevention of recurrent VTE is mentioned in the remit/appraisal objective in the NICE scope).

In terms of intervention, the criteria include "rivaroxaban vs any comparator" which is broader than the scope and the decision problem which specifies low molecular weight heparin+vitamin K antagonist (LMWH+VKA) as the comparator. Eligibility of specific efficacy and safety outcomes are not reported, so in theory the systematic review could have included outcomes that are outside the decision problem and scope (and does so – length of hospital stay and time in International Normalised Ratio [INR] range is reported in the MS – neither of these are specified in the NICE scope or decision problem).

Only RCTs were eligible for inclusion, though there was no restriction on inclusion based on any assessment of methodological quality or risk of bias. Setting was not used as an inclusion criterion.

The manufacturer does not make any statement about how closely their inclusion/exclusion criteria match the decision problem or NICE scope, and any other biases in their selection of studies.

## Economic Evaluation

### Manufacturer's Review of Published Economic Evaluations

The MS describes a systematic search of the literature which was conducted to identify economic evaluations of rivaroxaban using several health economic databases and medical databases. See section 3.1.1 on the ERG report, for the ERG critique of the search strategy. The review did not identify any studies that evaluated the cost-effectiveness of rivaroxaban specifically.

## Number of Source Documents

### Clinical Effectiveness

One randomised controlled trial was included.

### Cost-Effectiveness

- No published economic evaluations were identified.
- The manufacturer presented an economic model.

## Methods Used to Assess the Quality and Strength of the Evidence

### Expert Consensus

## Rating Scheme for the Strength of the Evidence

Not applicable

## Methods Used to Analyze the Evidence

### Review of Published Meta-Analyses

### Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The Evidence Review Group (ERG) report for this technology appraisal was prepared by Southampton Health Technology Assessments Centre (SHTAC) (see the "Availability of Companion Documents" field).

## Clinical Effectiveness

### Description and Critique of the Approach to Validity Assessment

The manufacturer has provided a tabulated quality assessment of the EINSTEIN-PE trial. The quality assessment follows the NICE criteria and is appropriate. Table 1 of the ERG report shows the ERG independent assessment of study quality and the manufacturer's submission (MS) assessment. The ERG generally agrees with the manufacturer's assessment.

One concern that the ERG has identified about the EINSTEIN-PE trial is that the trial population may not be fully representative of the pulmonary embolism (PE) patient population. The trial excluded patients with a creatinine clearance of  $<30$  mL/min, clinically significant liver disease, and a high risk of bleeding. The clinical expert consulted by the ERG stated that within their local clinical practice they treat a range of people with PE including some of those excluded from the trial, and the patient population in the trial is not wholly representative of the general treatment population. The ERG note that the trial excluded patients with severe renal failure (a creatinine clearance of 15-29 mL/min), who are a group at higher risk of bleeding according to the Summary of Product Characteristics (SmPC). However, the SmPC advises that rivaroxaban can be used with caution with these patients and recommends use of the standard dose, unless the risk of bleeding in these patients outweighs the risk for recurrent venous thromboembolism (VTE), in which case a lower dosage of 15 mg once daily is recommended after the first three weeks of treatment (instead of 20 mg once daily). As these patients are at a higher risk of bleeding and were excluded from the trial, it is possible that the trial may have underestimated the rate of bleeding that may be seen in clinical practice with rivaroxaban.

### Description and Critique of the Manufacturer's Approach to the Evidence Synthesis

The manufacturer presents a narrative review of the EINSTEIN-PE trial, including tabulated data. As only one study was identified as relevant to the review, a meta-analysis was not conducted.

See Table 2 of the ERG report for information on differences between the MS and trial publication in number of patients reported to have experienced the primary efficacy outcome, recurrent symptomatic VTE, in the intention-to-treat (ITT) population (see the "Availability of Companion Documents" field).

### Summary Statement of Manufacturer's Approach

The ERG's assessment of the quality of the systematic review included in the MS, based on the Centre for Reviews and Dissemination (CRD) criteria, is provided in Table 3 of the ERG report (see the "Availability of Companion Documents" field). The systematic review is of a good quality according to the CRD criteria. Publications were screened for inclusion based on title and abstract by two reviewers independently, which is considered to be a desirable approach in conducting systematic reviews for reducing the likelihood that relevant studies will be missed. It is implied that the full texts retrieved for further screening were also screened independently by two reviewers, but this is not clear. The processes used for data extraction and quality assessment (e.g., whether or not these were performed by one or more reviewers) are also not clear.

The evidence included in the review reflects the decision problem defined in the MS, although some additional outcomes from the EINSTEIN-PE trial were included which were not specified in the scope (e.g., net clinical benefit and health care resource utilisation). Overall, there is a low chance of systematic error in the systematic review based on the methods used by the manufacturer.

See section 3 of the ERG report for additional information on clinical effectiveness analysis (see the "Availability of Companion Documents" field).

## Economic Evaluation

### Cost-Effectiveness Analysis (CEA) Methods

Depending on the assumed anticoagulation treatment duration, the cost-effectiveness analysis uses either a 13- or 14-state Markov model to estimate the cost-utility of rivaroxaban compared to low-molecular-weight heparin+vitamin K antagonist (LMWH+VKA) in adults with an acute PE. Results are presented by duration of anticoagulation therapy (3 months/6 months/12 months/lifelong).

The 14 Markov model states are detailed in the MS. These states describe the management and complications of VTE and include an on-treatment state for the index event; two off-treatment states (off-treatment post index PE and off-treatment post deep vein thrombosis [DVT]); three recurrent event states (DVT, PE and PE post DVT); three acute bleeding states; and two long-term complication states. Disease progression is not explicitly modelled as DVT and PE are generally acute conditions not classified by severity.

The model has a lifetime horizon of 40 years and a cycle length of 3 months. Costs and outcomes are discounted at 3.5% per annum. The perspective of the model is the UK National Health Service (NHS)/Personal Social Services (PSS) and results are presented as incremental cost per quality-adjusted life year (QALY) gained.

One-way deterministic sensitivity analyses were performed for a large number of model parameters including treatment effects and utilities. Probabilistic sensitivity analyses (PSA) were also carried out.

The MS states that two clinical experts were approached early in model development to provide validation on the initial model structure and parameter values tested in the model. The MS notes that the expert comments were taken into account during the finalisation of the model structure, and that parameter values were refined following the literature review and results from EINSTEIN-PE. The model was also validated by comparison of its outcomes with those of EINSTEIN-PE.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

## Rating Scheme for the Strength of the Recommendations

Not applicable

# Cost Analysis

## Summary of Appraisal Committee's Key Conclusions

### Availability and Nature of Evidence

The manufacturer presented an economic model, which used clinical effectiveness data from EINSTEIN-PE and utility data derived through systematic review, and presented 4 base-case scenarios for 3-, 6-, 12-month treatments and a lifelong treatment analysis.

### Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

There is considerable variability and uncertainty surrounding service provision and the frequency of International Normalised Ratio (INR) monitoring that makes determining an accurate cost of INR monitoring problematic. The Committee took into account the clinical specialists' estimates, the deliberations during technology appraisal 261 and the Evidence Review Group (ERG)'s scenarios and concluded that the manufacturer's estimate of frequency of monitoring visits was too high and the ERG's scenarios were reasonable estimates.

The Committee considered that some of the studies that the manufacturer had used to obtain the utility values were too small and did not meet the reference case outlined in National Institute for Health and Care Excellence (NICE)'s Guide to the methods of technology appraisal. It concluded that the cost-effectiveness of rivaroxaban did not appear to be sensitive to the utility values used.

### Incorporation of Health-Related Quality-of-Life Benefits and Utility Values. Have Any Potential Significant and Substantial Health-Related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

The Committee heard from the patient expert who confirmed regular monitoring of INR, dose adjustment, multiple food and drug interactions with warfarin can impact on people's lifestyle can be costly and inconvenient. The manufacturer applied a disutility due to warfarin therapy of 0.012 in the low-molecular-weight heparin (LMWH)/vitamin K antagonist (VKA) arm.

### What Are the Key Drivers of Cost-Effectiveness?

INR monitoring costs. In the manufacturer's sensitivity analyses the cost-effectiveness of lifelong treatment with rivaroxaban was most sensitive to changes in the frequency of INR-monitoring visits, where the incremental cost-effectiveness ratio (ICER) increased from £13,252 per quality-adjusted life-year (QALY) gained to £27,914 per QALY gained if people have 3, rather than 5, visits in each quarter after the first. For lifelong treatment, the Committee considered the ERG's assumptions about the frequency of INR monitoring to be valid resulting in the ICER for lifelong treatment with rivaroxaban compared with lifelong treatment with a vitamin K antagonist after initial treatment with a LMWH increasing from £7070 in the ERG's amended base case to between £17,900 and £22,900 per QALY gained.

### Most Likely Cost-Effectiveness Estimate (Given as an ICER)

The Committee considered that in all scenarios assessed for the 3-, 6- and 12-month treatment durations, rivaroxaban either continued to dominate or the ICER compared with LMWH and a vitamin K antagonist could be considered a cost-effective use of National Health Service (NHS) resources. The most plausible ICER for lifelong treatment with rivaroxaban compared with lifelong treatment with a vitamin K antagonist after initial treatment with a LMWH was between £17,900 and £22,900 per QALY gained.

## Method of Guideline Validation

### External Peer Review

## Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the manufacturer of rivaroxaban and a review of this submission by the Evidence Review Group (ERG). For clinical effectiveness, one randomised controlled trial was the main source of evidence. For cost-effectiveness, the manufacturer's model and the additional economic analysis undertaken by the ERG were considered.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Appropriate use of rivaroxaban for treating pulmonary embolism (PE) and preventing recurrent venous thromboembolism (VTE)

### Potential Harms

The summary of product characteristics lists the following adverse reactions for rivaroxaban: anaemia, dizziness, headache, fainting, bleeding events, tachycardia (rapid heartbeat), low blood pressure, haematoma, stomach pain, dyspepsia (heartburn), nausea, constipation, diarrhoea, vomiting, pruritus (itching), rash, bruising, pain in the extremities, fever, and swelling, especially of the ankles and feet.

For full details of side effects and contraindications, see the summary of product characteristics available at <http://emc.medicines.org.uk/>

## Qualifying Statements

### Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

## Implementation of the Guideline

### Description of Implementation Strategy

- Section 7(6) of the National Institute for Health and Care Excellence (NICE) (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, National Health Service (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
- When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraph above. This means that, if a patient has a pulmonary embolism and the doctor responsible for their care thinks that rivaroxaban is the right



treatment, it should be available for use, in line with NICE's recommendations.

- NICE has developed tools to help organisations put this guidance into practice (listed below). These are available on the NICE Web site (<http://guidance.nice.org.uk/TA287> ).
- Costing template and report to estimate the national and local savings and costs associated with implementation.

## Implementation Tools

Clinical Algorithm

Foreign Language Translations

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Staying Healthy

### IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Rivaroxaban for treating pulmonary embolism and preventing recurrent venous thromboembolism. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. 46 p. (Technology appraisal guidance; no. 287).

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2013 Jun

## Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

## Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

## Guideline Committee

Appraisal Committee

## Composition of Group That Authored the Guideline

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## Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) . Also available for download in ePub and eBook formats from the [NICE Web site](#) .

## Availability of Companion Documents

The following are available:

- Copley V; Pickett K, Cooper K, Shepherd, J Rivaroxaban for the treatment of pulmonary embolism and the prevention of recurrent venous

thromboembolism. Evidence review group report. Southampton Health Technology Assessments Centre (SHTAC); 2012 Feb. 93 p.  
Electronic copies: Available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) .

- Rivaroxaban for treating pulmonary embolism and preventing recurrent venous thromboembolism. Costing template. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. (Technology appraisal 287). Electronic copies: Available from the [NICE Web site](#) .

## Patient Resources

The following is available:

- Rivaroxaban to treat pulmonary embolism and to prevent further venous thromboembolism. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. 6 p. (Technology appraisal 287). Electronic copies: Available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) . Also available in Welsh from the [NICE Web site](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

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